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SGM 6934.1
PATENT

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**** FOR DISCUSSION PURPOSES ONLY ****

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Brian W. Ward et al.

Art Unit: 1655

Serial No.: 09/610,935

Filed: July 6, 2000

Confirmation No. 5148

For: TARGET REAGENTS THAT ENHANCE REACTION-PRODUCT ANALYSIS

Examiner: Bradley L. Sisson

February 20, 2002

AMENDMENT B

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS,

Sir:

In response to the Office action issued on November 1, 2001, applicants respectfully submit the following amendments and remarks in connection with the above-identified application.

IN THE CLAIMS:

Please cancel claims 1-10, 12, 17, 18, and 23-41.

Please amend claim 11 as follows:

11. (amended) A composition comprising a polymerase for an *ex-vivo* enzymatic reaction in which a nucleic acid polymer product complementary to a nucleic acid polymer template is prepared, and a tracer dye compatible with the polymerase, the composition being substantially free of the nucleic acid polymer template and
5 having an optical density greater than about 5 at a visible wavelength of maximal tracer absorbance.

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Please amend claim 21 as follows:

21. (amended) The composition of claim 12 wherein the tracer dye is comprised of acid violet 5 and acid red 1.

Please amend claim 22 as follows:

22. (amended) The composition of claim 14 wherein the optical density of the composition is about 200 - 400 at a visible wavelength of maximal tracer absorbance, the polymerase is a Taq polymerase, and the tracer dye consists of 20% acid violet 5 and 80% acid red 1.

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REMARKS

Upon entry of this amendment, claims 11, 13-16, and 19-22 are pending in the application. Support for the amendment to claim 11 can be found in claims 12 and 18.

Reconsideration is requested of the rejection of claims 1-22 and 34-41 under 35 U.S.C. §112, first paragraph, on the asserted basis that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention.

While applicants maintain that the invention defined by claims 1-10 and 34-41 meet the written description requirement of 35 U.S.C. §112, first paragraph, for the reasons stated in Applicants' Response Under 37 C.F.R. 1.111 (Paper No. 6), filed on August 1, 2001, this portion of the rejection is presently moot in view of the cancellation of these claims. Applicants, however, reserve the right to pursue the canceled subject matter in its full scope in a continuation application. As to the remaining subject matter, *i.e.*, claims 11, 13-16, and 19-22, as amended, applicants request reconsideration.

In the specification of their application, applicants describe one embodiment of their invention as a composition comprising a reagent which is essential for an enzymatic reaction and a tracer which is compatible with the enzyme.

Examples include any ligase, phosphodiesterase, DNase, exonuclease, RNase, phosphatase, kinase, terminal transferase, reverse transcriptase, restriction endonuclease, RNA polymerase, and DNA polymerase. Enzymes which are preferred for use with this invention are restriction endonucleases and DNA polymerases. More preferred are DNA polymerases; even more preferred are any thermostable DNA polymerase; most preferred is wild-type or modified Taq polymerase.¹

* * *

Preferred are tracers which impart a visual signal. The most preferred tracers are dyes which are colored under the conditions that the analysis is performed. Any color dye which is visible during the post-reaction

¹Applicants' specification at page 12, lines 1-9.

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analysis can be used ; preferred are dyes which have a peak visible absorbance wavelength at between 430 and 617 nm; most preferable dyes have a peak visible absorbance wavelength at between 500 and 535 nm.²

Example 1 describes in detail the preparation of a composition containing Taq polymerase and a dye tracer. When Example 1 is read in combination with the remainder of the specification, therefore, a person of ordinary skill would be left with the firm and definite understanding that the inventors were in possession of the invention defined by claim 11.

The remainder of the pending claims depend from claim 11 and impose additional requirements. Claim 20, for example, requires that the polymerase of claim 11 be Taq polymerase. Claim 22, for example, requires that the polymerase be Taq polymerase and that the tracer dye consists of 20% acid violet 5 and 80% acid red 1. The Office cannot seriously maintain that the inventors were not in possession of the invention defined by these claims.

In any event, entry of this amendment is requested pursuant to 37 C.F.R. 1.116. Applicants have merely canceled certain claims and presented other claims in better form for consideration on appeal.

²Applicants' specification at page 13, lines 9-17.

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VERSION WITH MARKINGS SHOWING CHANGES MADE

IN THE CLAIMS:

Claims 1-10 have been canceled.

Claim 11 is amended as follows:

11. (amended) A composition comprising a polymerase [reaction component essential] for an *ex-vivo* enzymatic reaction in which a nucleic acid polymer product complementary to a nucleic acid polymer template is prepared [a substrate is catalyzed by an enzyme in a reaction mixture to form a product], and a tracer dye compatible with the polymerase [enzyme], the composition being substantially free of the nucleic acid polymer template [substrate] and having an optical density greater than about 5 at a visible wavelength of maximal tracer absorbance.

Claim 21 is amended as follows:

21. (amended) The composition of claim 12 wherein the tracer dye is comprised of acid violet 5 and acid red 1.

Claim 22 is amended as follows:

22. (amended) The composition of claim 14 wherein the optical density of the composition is about 200 - 400 at a visible wavelength of maximal tracer absorbance, the [reaction component essential for a] polymerase [reaction] is a Taq polymerase, and the tracer dye consists of 20% acid violet 5 and 80% acid red 1.

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CONCLUSION

A check in the amount of \$110.00 for a one month extension of time is enclosed.
The Commissioner is hereby authorized to charge any under payment or credit any
over payment to Deposit Account No. 19-1345.

Respectfully submitted,

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